



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0835]

Withdrawal of Approval of New Animal Drug Applications; Diethylcarbamazine; Nicarbazine; Penicillin; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843, email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Phibro Animal Health Corp., 65 Challenger Rd., 3d Floor, Ridgefield Park, NJ 07660 has requested that FDA withdraw approval of NADA 098-371 for use of nicarbazine, penicillin, and roxarsone in 3-way, combination drug Type C medicated feeds for broiler chickens and NADA 098-374 for use of nicarbazine and penicillin in 2-way, combination drug Type C medicated feeds for broiler chickens because the products are no longer manufactured or marketed.

R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518 has requested that FDA withdraw approval of NADA 123-116 for Diethylcarbamazine Citrate Capsules used in dogs for the prevention of heartworm disease because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADA 098-371, NADA 098-374, and NADA 123-116, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these applications.

Dated: August 19, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.